



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/776,682

02/10/2004

Rodolfo A. Morales

578492000510

3785

25226 7590 01/12/2009
MORRISON & FOERSTER LLP
755 PAGE MILL RD
PALO ALTO, CA 94304-1018

EXAMINER

RYCKMAN, MELISSA K

ART UNIT

PAPER NUMBER

3773

MAIL DATE

DELIVERY MODE

01/12/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/776,682	Applicant(s) MORALES ET AL.	
	Examiner MELISSA RYCKMAN	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37-58 is/are pending in the application.
- 4a) Of the above claim(s) 49-58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to claims filed 10/22/08.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 37 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The first and second tethered clip assembly is in a closed tissue-piercing position in both the first and second deployed configuration, with the second deployed configuration having the two clips closer to each other. The examiner would like to remind the applicant that the originally filed species included "at least one clip is configured to penetrate tissue" therefore any changed must be directed to this species.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 3773

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 37-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoon (U.S. Patent No. 5984933).

Claim 37: Yoon teaches a device for applying at least one clip to annular tissue of a heart valve (capable of being used to clip annular tissue of a heart) the device comprising; a shaft having a proximal end and a distal end (Fig. 48); and at least one actuator (2460) at or near the proximal end of the shaft for causing the device to advance the tethered clip assembly from the shaft (Fig. 49), wherein the tethered clip assembly has a first deployed configuration and a second deployed configuration, the tethered clip assembly in the first deployed configuration comprising at least two clips separated by a greater distance than when in the second configuration, the tether is under longitudinal tension and the first distance is reduced, the two clips are in a closed tissue-piercing position when the tethered clip assembly is in both its first and second deployed configuration (Yoon teaches deploying the clips Fig. 38, when the tether is under tension the distance will be reduced).

Claims 38-40: Yoon teaches the device further comprises a clip crimping member (distal portion of 2440, Fig. 28), a plurality of clips (Fig. 48), each plurality of clips is couple to the tether (Fig. 48).

Claim 41: Yoon teaches at least one clip is T-shaped (see Fig. 44, if 2241 plane is shown, a T is formed out of 2240 and 2241)

Claims 42 and 43: Yoon teaches each of the plurality of clips includes two eyelets (2228), and the tether (2218a and 2218) has parallel segments passing through both eyelets of each clip (Fig. 44).

Claim 44: Yoon teaches a system for applying at least one clip to annular tissue of a heart valve, comprising: the device as claimed above in claim 37; and a stabilization device to capture and immobilize the annular tissue relative to the remainder of the heart (2232, Fig. 44, this inner face of the clip immobilizes the tissue).

Claims 45,46 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon (U.S. Patent No. 5984933), as applied to claim 37 above, in view of Crowley (U.S. Patent No. 5524630).

Regarding claim 45 and 46 Yoon discloses the claimed invention except for a visualization device adapted to directly view a valve annulus in a heart chamber and a visualization device comprising an ultrasonic imaging transducer. However, Crowley teaches a visualization device adapted to directly view a valve annulus in a heart chamber (Fig. 30) and a visualization device comprising an ultrasonic imaging transducer (Fig. 3 and 4).

It would have been obvious to one of ordinary skill in the art to include a visualization device at the end of the claimed invention to insure proper installation of the clips during surgery.

Art Unit: 3773

Regarding claim 48 Yoon discloses the claimed invention except for a transparent element comprising a transparent balloon inflatable with a transparent inflation medium, however Crowley teaches a transparent balloon inflatable with a transparent inflation medium (col.4 ll.35, col. 17 ll. 6).

It would have been obvious to one of ordinary skill in the art to include a balloon at the end of the element to occlude blood flow, as this is common within the art.

Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon (U.S. Patent No. 5984933) and Crowley (U.S. Patent No. 5524630) as applied to claim 45 above, further in view of Johnson (5766240).

Regarding claim 47 Yoon discloses the claimed invention except for an optical viewing element, however Johnson discloses an optical viewing element (col. 15 ll.44) disposed in a transparent element (col. 5 ll. 11).

It would have been obvious to one of ordinary skill in the art to include an optical viewing element to insure proper installation of the clips during surgery.

Response to Arguments

Applicant's arguments filed 10/22/08 have been fully considered but they are not persuasive. The applicant generally argues the following:

- The device of Yoon fails to teach the tether is under longitudinal tension and the first distance is reduced to a second distance.

Art Unit: 3773

The examiners position is when the tether of Yoon is under tension the distance will be reduced, under certain usage the distance of the clips would inherently occur.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA RYCKMAN whose telephone number is (571)272-9969. The examiner can normally be reached on Monday thru Friday 7:30-4:00.

Art Unit: 3773

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571)-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MKR

/Melissa Ryckman/
Examiner, Art Unit 3773

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773